

**SUMMARY RECORD OF THE
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH**

HELD IN BRUSSELS ON 8 JUNE 2007

(Section GM Food & Feed and Environmental Risk)

President: Michael Flueh

All Member States were present.

1. Discussion on the implementation of the labelling provisions of Regulation (EC) No 1829/2003 with respect to breeding stacks.

A working document entitled "labelling threshold for GM food and feed and stacked events" was presented by a Commission representative. This document was welcomed by the Committee and considered as a valuable basis for the harmonisation of controls of the labelling provisions of Regulation (EC) No 1829/2003. A majority of the delegations agreed with the principles outlined in the document. Some delegations pointed out that some aspects could be further developed to reach further harmonisation.

On the basis of this discussion, the Commission will now consider the appropriate next steps with a view to harmonise the implementation of the labelling provisions of Regulation (EC) No 1829/2003 with respect to breeding stacks.

2. Information from the Commission on pending applications.

A Commission representative informed the Committee on the current state-of-play with respect to pending applications that have received favourable European Food Safety Authority opinions. Draft decisions regarding these applications should be submitted to the Committee after the summer.

3. Information from the Commission on the outcome of one mission from the FVO in Argentina.

The mission was undertaken to evaluate control systems for food, feed and seed consisting of or produced from genetically modified organisms (GMO) intended for export to the EU and took place in Argentina from 21 to 28 November 2006. It was the first mission on this subject to a third country. Argentina accounts for approximately 50% of maize and soya imports into the EU.

Findings

There is a clearly defined regulatory system in place for the authorisation of GMO. This system is the basis of preventing the circulation of unauthorised GMO in Argentina and potential export in food, feed or seed to the EU. Controls on GMO exports to the EU are based on the Argentinean authorisation procedure which allows for commercial cultivation of 10 GMO events all of which are authorised in the EU. Non GMO exports such as red flint maize (for food use) are controlled by industry on a voluntary basis. Such products are certified as non GMO by private bodies pre export based on contractual arrangements with EU buyers. Organic produce is certified as GMO free by competent authorities prior to export.

4. State of play on BT63 Rice (China) and DAS-59122 Maize (USA).

The Committee was informed that no rapid alerts were notified since the last meeting, that the Director General of DG SANCO raised during his visit to Chinese control authorities the concerns of the EU as regards the recent rapid alerts as well as regards the difficulty to get enough material to validate the method and details of the method itself.

The Committee was informed about the lots that were found to contain DAS-59122 maize and that had been subject to messages through the Rapid Alert System for Food and Feed. Before these findings, DAS-59122 maize was not detected during the controls made either at import level or on products present on the EU market. Member States where such lots have been found informed the committee of the measures that were taken to prevent or limit the placing on the market of the products that could be traced.

The chairman of the Committee reminded the Member States of the necessity to increase the frequency of their controls with respect to the products that have a risk to contain this GMO.

5. Examination and possible opinion on a draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Document SANCO/964/2007 Rev.2)

A draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

Vote: no opinion (214 votes in favour, 83 against, 48 abstentions)

The following considerations were mentioned as reasons for not supporting the draft decision:

- products others than food and feed containing or consisting of GMOs are not within the scope of EU-Regulation EC No 1829/2003;
- the EFSA opinion is not considered as fully satisfactory;
- the negative public opinion with respect to GMO;
- the difficulties to apply the labelling threshold for GM food and feed and stacked events.

Two delegations provided written declarations (see hereunder).

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Declaration from the delegation of Austria

Austria objects the placing on the market of genetically modified maize 1507xNK603 due to the following reasons:

- *From the Austrian point of view, products others than food and feed containing or consisting of DAS-01507-1xMON-00603-6, are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*
- *The risk assessment which has been carried out lacks a lot of data and is not suitable to give a scientific proof for the safety for human and animal health as well as the environment.*

Due to the lack of an event-specific detection-method for the stacked event, Austria is of the opinion that for interpreting the quantitative analysis of the stacked-event the additional concept shall be used.

Declaration from the delegation of Greece

In general Greece believes that the risk assessment is not sufficiently examined and presented.

Toxicology

We insist that an additional 90-day feeding study in rats with whole GM plants of the hybrid in question should be carried out to further complete its safety assessment. The fact that studies for each of the parental line (1507, NK603) have been carried out and therefore additional subchronic toxicity studies with 1507xNK603-maize is not considered as necessary cannot be regarded as appropriate.

Compositional analysis

The compositional data of 1507xNK603 and the traditional control maize demonstrated statistically significant differences for many nutrients (fatty acids, vitamins and minerals) across locations. It is necessary to include a comparison table of proteins, fat, vitamins, minerals, etc. to show these differences and determine their significance. Moreover, we consider that additional samples for further analysis, harvested from different field experiments are necessary in order to ensure the equivalence of the GM food / feed with the traditional maize.

Molecular Characterization

A detailed description of the insertion site including sequence data of the inserted material and of the flanking regions, in order to avoid rearrangements has not been conducted for the hybrid in question.

Field Trials

Field trials should cover more than one representative growing season and multiple geographical locations representative of various climatic conditions to provide useful information on the protein levels of CRY1, PAT and CP4 EPSPS throughout the growth and development of the maize. The file on the 1507xNK603 maize includes data on field trials that were conducted only in three regions of Chile (Buin, Linderos and Viluco) for one growing season (2002-2003). However, field trials have already been performed in France (2003) and Spain (2003, 2004) according to the submitted application. We believe that these data should be provided. Moreover, data on field trials conducted in at least one more growing season should be provided as well.

Greece is of the opinion that still the environmental risk assessment can not be regarded as sufficient.

Quantification and Labelling.

Problems will arise with the labelling (the 0.9% threshold is not applicable) and the quantification of the hybrid in question. The lack of event specific method for the direct detection of the hybrid leads to over - estimation or sub - estimation of the percentage of the GM DNA. On the other hand the simultaneous detection of both events in a single seed is not considered to be a practical solution.

Finally Greece is of the opinion that the paragraph 2c and ANNEX b3 must be clarified further otherwise be removed from the text because are not covered by the scope of the Reg 1829/2003 (art 1 and 15).

6. Examination and possible opinion on a draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Document SANCO/965/2007 Rev.2)

A draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

Vote: no opinion (214 votes in favour, 86 against, 45 abstentions)

The following considerations were mentioned as reasons for not supporting the draft decision:

- products others than food and feed containing or consisting of GMOs are not within the scope of EU-Regulation (EC) No 1829/2003;
- the EFSA opinion is not considered as fully satisfactory. Some delegations referred more specifically to the toxicological assessment;
- the negative public opinion with respect to GMO;
- the difficulties to apply the labelling threshold for GM food and feed and stacked events.

Two delegations provided written declarations (see hereunder).

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Declaration from the delegation of Austria

Austria objects the placing on the market of genetically modified maize NK603xMON810 due to the following reasons:

- *From the Austrian point of view, products others than food and feed containing or consisting of MON-00603-6xMON-00810-6, are not within the scope of EU-Regulation (EC) No 1829/2003 but under Directive 2001/18/EC.*
- *The risk assessment which has been carried out lacks a lot of data and is not suitable to give a scientific proof for the safety for human and animal health as well as the environment. Furthermore Austria has issued a ban for the import of the single event maize MON810.*
- *Due to the lack of an event-specific detection-method for the stacked event, Austria is of the opinion that for interpreting the quantitative analysis of the stacked-event the additional concept shall be used.*

Declaration from the delegation of Greece

In general Greece believes that the risk assessment is not sufficiently examined and presented. More specific:

Toxicology

We insist that an additional 90-day feeding study in rats with whole GM plants of the hybrid in question should be carried out to further complete its safety assessment. The fact that studies for each of the parental lines (MON810, NK603) have been carried out and therefore additional subchronic toxicity studies with NK603 x MON810-maize is not considered as necessary cannot be regarded as appropriate (taking also into consideration the results of the subchronic toxicological studies in rats of the MON863xMON810xNK603 hybrid).

Molecular Characterization

According to the Technical Dossier, only southern blot experiments have been performed to conclude that the structure and organization of the inserts found in NK603xMON810 maize are equivalent to those present in NK603 and MON810 maize respectively. However, we would like to know which experimental data prove that the flanking sequences of the two inserts in the hybrid NK603xMON810 are the same as in the two parental lines.

Field Trials

Field trials in different climatic conditions provide useful information on the protein levels of cry1Ab and cp4 epsps throughout the growth and development of the maize. The file on the NK603xMON810 maize includes data on field trials that were conducted at three sites in France during one growing season (2000). The mean level of the CP4 EPSPS protein across all sites in forage samples from the NK603xMON810 and the single-trait NK603 transgenic maize hybrid was comparable. However, a sound variability of the expression level of this protein within NK603 and NK603xMON810 is observed. Therefore, an explanation for the wide range of values for the CP4 EPSPS levels and the resulted high standard deviation should be provided. Given that field trials have already conducted in USA, the data on the CP4 EPSPS expression levels would be useful.

Quantification and Labelling

Problems will arise with the labelling (the 0.9% threshold is not applicable) and the quantification of the hybrid in question. The lack of event specific method for the direct detection of the hybrid leads to over - estimation or sub - estimation of the percentage of the GM DNA. On the other hand the simultaneous detection of both events in a single seed is not considered to be a practical solution.

Finally Greece is of the opinion that the paragraph 2c and ANNEX b3 must be clarified further otherwise be removed from the text because are not covered by the scope of the Reg (EC) No 1829/2003 (art 1 and 15).

7. Examination and possible opinion on a draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Document SANCO/1628/2007)

The draft Commission Decision was presented. A majority of Member States indicated that they were in a position to support the draft. Some delegations stressed the importance of authorising this product for their livestock sector.

Some delegations indicated that they could not support the draft. The elements put forward by these delegations were that they consider that products others than food and feed containing or consisting of GMOs are not within the scope of EU-Regulation (EC) No 1829/2003 or that they are not fully satisfied with the EFSA opinion or the negative public opinion with respect to GMO.

The chairman of the meeting postponed the vote to another meeting of the Standing committee and invited Member States who indicated that they would abstain, in some cases pending new information, to reconsider their position.

8. Other business

Presentation by a delegation of Argentina of a certification scheme for their exports of GM maize

Since 18 April 2007, the tolerance for the adventitious or technically avoidable presence of GA21 maize in grains at a level below 0.5% is no more applicable. Since GA21 maize was cultivated in limited amounts in Argentina, it is present in some of the lots of maize that are currently stored in Argentina.

A delegation of Argentina presented in detail a certification scheme aiming to prevent the presence of GA21 maize in its exports to the European Union. This certification relies on controls that will be made on samples taken in accordance with Recommendation (EC) No 787/2004. The analysis will be carried out by an official laboratory that is accredited for performing PCR analysis. The Argentinean authorities will deliver, on request of industry, a certificate for each lot for which GA21 was not detected following this scheme.

In addition to these measures, the committee was also informed that the commercialisation and/or circulation of seeds of GA21 maize were prohibited as from the new season.

The committee welcomed the presentation and thanked the Argentinean authorities for their efforts to prevent the export of illegal GMO to the European Union. After a discussion on some technical aspects, the Argentinean delegation indicated that it would bring some clarifications to the documents describing their certification scheme. This reviewed document will be sent to Member States through the Commission.

The chairman of the Committee asked Member States to inform their respective border inspection posts of this certificate. It has been noted that the system was not officially endorsed by the Commission and that Member States have still responsibility to control.

Codex Task force on Modern Biotechnology

A Commission representative provided a state-of-play of the different works ongoing within the Codex task force on Modern Biotechnology. He drew the attention of the Member States to the various circular letters for which a contribution from the European Community should be considered.